BIOPOLYMER INTERNATIONAL

ASSOCIATION MONDIALE DES PRODUCTEURS DE BIOPOLYMERES ALIMENTAIRES
WORLD ASSOCIATION OF FOOD GRADE BIOPOLYMER PRODUCERS

Mr Arthur Neal, Director, Program Administration
National Organic Program
USDA–AMS—TMP–NOP
1400 Independence Ave., SW., Room 4008
So. Ag Stop 0268
Washington, DC 20250

Via E-mail: National.List@usda.gov

11th August 2005

Dear Mr Neal,

RE: USDA, Agricultural Marketing Service Docket Number TM-04-07 concerning 7 CFR Part 205, National Organic Program Sunset Review process

Biopolymer International[1], the non-governmental world wide association of food grade biopolymer producers, would like to thank the United States Department of Agriculture and the National Organic Standards Board for the opportunity to make the following comments on the Sunset Review of the 2002 National List.

Biopolymer asks for continuance of the following item as it is listed on the National List. For many years, we have provided xanthan gum to our customers for their organic product formulations and would like to provide support the following materials:

> **XANTHAN GUM:** § 205.605 Non-agricultural (non-organic) substances allowed as ingredients in or on processed products labelled as ‘‘organic’’ or ‘‘made with organic (specified ingredients or food groups(s))” (b) Synthetics allowed.
> Xanthan gum is a polysaccharide produced via bacterial fermentation using naturally occurring nutrients sources. In that xanthan gum is a natural extra cellular polysaccharide not only should it remain on the list, but the NOP should consider reclassifying xanthan gum to a non-synthetic as per §205.605 (a): non-synthetic.

Biopolymer International recommends that xanthan gum remain on the list as per the original evaluation by the NOSB, that xanthan gum is:

(1) Not harmful to human health or the environment
(2) Necessary because of the unavailability of alternatives
(3) Consistent and compatible with organic practices

Substantial safety and toxicology (mammalian and eco-toxicity) data exists with JECFA and US FDA that xanthan gum is not harmful to human health or the environment. Xanthan gum is used by formulators of organic products and has been reviewed for its unique applications in organic food and beverage formulations.

[1] The member companies of Biopolymer International are: ADM, CP Kelco, Danisco, Degussa, Deosen and Jungbunzlauer.

AVENUE DES GAULOIS, 9 – B-1040 BRUSSELS
TEL: +32/2.736.53.54 – FAX: +32/2.732.34.27
BIOPOLYMER@ECCO-EU.COM
WWW.BIOPOLYMER-INTERNATIONAL.COM

Specific reference to questions asked in FR (Appendix)

CATEGORY 1 - No adverse impacts on humans or the environment

1. Xanthan gum does not contribute any adverse impact to the environment or humans either during production or end-use. During the manufacturing processes, any waste will be discharged to the municipal sewage treatment plant and will be present in only trace amounts.
2. There is no significant impact on the environment from xanthan gum. Polysaccharides are degraded by micro-organisms found in the water and soil. Therefore, they do not persist in the environment. Minerals will naturally degrade. Any waste materials (e.g., finished products such as food or beverages) will be composted, sent to land fills or treated in wastewater treatment plants. These actions will not result in an adverse effect on the environment.
3. Xanthan gum is not on, nor does it contain, inerts from list 1, 2 or 3.
4. There is no potential for detrimental chemical interaction with other materials used.
5. There are no adverse biological and chemical interactions in agro-eco-systems.
6. There are no detrimental physiological effects on soil organisms, crops, or livestock.
7. There is no toxic or other adverse action of the material or and there are no breakdown products.
8. There is no undesirable persistence or concentration of the material or breakdown products in the environment.
9. There are no harmful effects on human health.

Xanthan gum has a safe history of use as a food additive worldwide and is recognized by the World Health Organization Joint Expert Committee for Food Additives as safe. JECFA as well as the European Community Scientific Committee for Food have established an Acceptable Daily Intake (ADI) of 'not specified (NS),' the highest rating given to an ingredient for which no toxic effects were observed, which show the ingredients to be safe for consumption in the human diet.

CATEGORY 2 - Substances are essential for organic production.

Xanthan Gum is produced from natural sources, e.g. bacterial fermentation using naturally occurring nutrients. It is produced from natural constituents and contributes a unique attribute to foods and beverages, thus allowing many more organic products to be formulated and marketed to the consumer. Xanthan gum is used in various food and beverage formulations such as batters, baked goods, bakery and pie filings, beverages, confectionary, dairy products, desserts, dietetic foods, dressings, dry mixes, flavour emulsions, frozen foods, icings and frostings, relish, retorted products, sauces and gravies, syrups and toppings.

The mode of action is as a thickener, stabiliser and emulsifier with texturizing attributes. The typical amounts of xanthan gum used is small (less than 1.0%) of the processed food because of the self-limiting nature, which is the concentration of substance above at which will result in an inedible or unusable product.

Xanthan gum may also be used personal care products, such as body washes, sunscreen/lotions, skin hydration sprays, oral care, toothpaste, and mouthwash. Additional uses of the substances are found in consumer products, such as liquid detergents, cleaners, suspensions and films.

CATEGORY 3 - Substances are compatible with organic production practices

Xanthan Gum is listed at § 205.605

AVENUE DES GAULOIS, 9 – B-1040 BRUSSELS
TEL: +32/2.736.53.54 – FAX: +32/2.732.34.27
BIOPOLYMER@ECCO-EU.COM
WWW.BIOPOLYMER-INTERNATIONAL.COM

BIOPOLYMER INTERNATIONAL

ASSOCIATION MONDIALE DES PRODUCTEURS DE BIOPOLYMERES ALIMENTAIRES
WORLD ASSOCIATION OF FOOD GRADE BIOPOLYMER PRODUCERS

Yours sincerely,

Dr Robert Winwood

President, Biopolymer International

AVENUE DES GAULOIS, 9 – B-1040 BRUSSELS
TEL: +32/2.736.53.54 – FAX: +32/2.732.34.27
BIOPOLYMER@ECCO-EU.COM
WWW.BIOPOLYMER-INTERNATIONAL.COM